DETAILED ACTION

The amendment filed June 10, 2010, has been received and entered.

Claims 11-16 are cancelled. Claims 17-22 are new. Claims 1-10 and 17-22 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the recitation "*Thermomyces languginosas*," which appears to be a misspelling of the species name "*Thermomyces lanuginosa.*" Also, claim 1 is rendered indefinite by the recitation that the *Thermomyces lanuginosa* lipase has an activity of "at least 250 IUN" at the onset of the process. Page 15, lines 29-32 of the specification teaches that the interesterification activity of a lipase catalyst is defined as the initial conversion rate for tristearin at standard conditions, wherein 1 IUN is defined as the conversion rate of "0.01 g tristearin/l/minute/gram catalyst." Therefore, it is clear that for any measure of IUN units to be detected, a lipase must be in a catalyst. However, claim 1 does not speak of exposing the triglyceride fat to a catalyst comprising a *Thermomyces lanuginosa* lipase. Therefore, it is unclear how the lipase can have an activity in IUN units. Thus, claims 1-10 and 17-22 are rejected under 35 U.S.C. 112, second paragraph.

Claims 2, 4, 17 and 19 are rendered indefinite by the recitation of "catalyst" since it lacks antecedent basis. Parent claim 1 does not speak of any "catalyst."

Claim 5 is confusing since it is unclear how passing the reaction mixture through a packed catalyst bed reactor relates to exposing the triglyceride fat in the reaction mixture to a *Thermomyces lanuginosa* lipase. It is unclear whether the packed catalyst bed reactor comprises the lipase.

Claim 10 is rendered indefinite by the recitation "The processProcess," which should be replaced with phrase "The process."

Claim 19 is indefinite since the phrase "0.05-3 wt.% calculated on the reaction mixture" is confusing. It is unclear what the reference to the reaction mixture is meant. It appears that the weight percentage is calculated on the basis of the reaction mixture weight.

Claim 20 is confusing since it is unclear how the process is carried out by passing the reaction mixture through a packed catalyst bed reactor. It is unclear how the packed catalyst bed reactor relates to lipase of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-10, 17-19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2003/0054509) in light of Sullivan et al. (US 5,391,383) and Zhang et al. (JAOCS. 2001. 78(1): 57-64. Listed on 9/17/07 IDS).

Lee et al. discloses contacting a mixture comprising glycerides with lipase to effect esterification or transesterification. See claim 1. In the process, the lipase modifies the physical properties of the glycerides by randomization (page 3, paragraph [0034]). The resulting product can be used in food products such as margarine, shortening, and other confectionary fats (page 7, paragraph [0072]).

Examples 1 and 4 of Lee et al. are most closed related to the invention as claimed of the instant application. For both Examples 1 and 4, the lipase is provided as Novozymes' Lipozyme TL IM. Zhang et al. teaches that Lipozyme TL IM comprises an immobilized *sn*-1,3-specific lipase from *Thermomyces lanuginosa* wherein the lipase is silica-granulated (page 57, first column, second paragraph and page 58, first column, first full paragraph). Note further that the specification as filed indicates Lipozyme TL IM as the preferred catalyst comprising a Thermomyces lanuginosa lipase (page 10, lines 10-13). Therefore, the randomization performed

by Lee et al. in at least Examples 1 and 4, occurs over the terminal and middle positions of the fatty acid residues on the glyceride moiety.

Example 1 teaches one aspect of the Lee invention, where the Lipozyme TL IM lipase is packed into a column, thus forming a packed bed reactor (page 7, paragraph [0077]). The substrate is a mixture of fully hydrogenated soy oil and liquid soy oil, and said substrate is pumped through the packed bed reactor at a temperature of 65°C for the reaction (page 8, paragraph [0077]). As a mixture of fully hydrogenated soy oil and liquid soy oil is taught in the instant specification as comprising triglycerides (page 15, lines 14-21), Example 1 is drawn to treating a triglyceride fat with a *Thermomyces lanuginosa* lipase as required by instant claim 1. Moreover, Example 1 of Lee et al. meets the temperature limitation of instant claims 10 and 22.

Just as in Example 1, Example 4 teaches treating a triglyceride fat (provided by mixture of fully hydrogenated soy oil and liquid soy oil) with a *Thermomyces lanuginosa* lipase. Specifically, Example 4 teaches the treatment of 400 g of a mixture of fully hydrogenated soy oil and liquid soy oil with 40 g of Lipozyme TL IM lipase at a temperature of 70°C in a batch reactor (page 8, paragraph [0082]). The lipase is about 9 wt.% of the reaction mixture (40 g lipase/(400 g oil + 40 g lipase) * 100), thus the catalyst amount limitation in instant claim 4 is met by the reference.

When speaking of its method in general, Lee et al. teaches that the mixture treated with the lipase, the initial substrate, can be a mixture of compounds of one or more glycerides (page 1, paragraph [0012]) where the glycerides can be selected from coconut oil, palm oil, triglycerides, and partial or fully hydrogenated oils (page 1, paragraph [0013]). Thus, the initial substrate can be any triglyceride fat which has not been subjected to hydrogenation. According to Sullivan et

al., coconut oil is a lauric fat (column 7, line 39), so Lee et al. teaches an initial substrate of a mixture of palm fat and lauric fat when the mixture is of palm oil and coconut oil. Furthermore, the examples of Lee et al. teach an initial substrate of fully hydrogenated soy oil and liquid soy oil (page 8, paragraph [0077] and [0082]). Therefore, Lee et al. also teaches an initial substrate of a mixture of a liquid oil and a hydrogenated oil. In sum, the limitations of instant claim 6 regarding the specific triglyceride fat are taught by Lee et al.

Lee et al. differs from the claimed invention in that it does not teach that the lipase has an activity of at least 250 IUN at the onset of the process. However, the creation of Lipozyme TL IM of different enzyme activities would have been a routine matter of experimentation, as the skilled artisan would have recognized that the properties of the fats/oils produced would have varied according to enzymatic activity. Therefore, the lipase activity level recited in the instant claims (at least 250 IUN, at least 300 IUN, at least 350 IUN) would have been rendered obvious.

Lee et al. also does not teach the conversion degree on the terminal positions, Re, and the conversion degree on the middle position, Ra, recited in the instant claims. However, Lee et al. teaches that lipase enzymatic activity is affected by factors such as temperature, light, and moisture content (page 6, paragraph [0060]) and that flow rate, column residence time, and substrate mixture temperature can be adjusted to optimize enzymatic activity (page 7, paragraph [0071]). Given that Lee et al. teaches using the same lipase (Lipozyme TL IM) as used in the instant specification, that the recited initial enzymatic activity level is rendered obvious (at least 250 IUN, at least 300 IUN, at least 350 IUN; see preceding paragraph), and that various parameters can be altered through routine experimentation to optimize lipase enzymatic activity, the conversion degrees Re and Ra recited in the instant claims would have been rendered

obvious. It is a matter of routine optimization and experimentation. As Lee et al. indicates that moisture content affects lipase enzymatic activity, it would have been obvious to have varied the water content, testing various water content levels including those recited in instant claims 1 and 9. Thus, claims 1-4, 6-10, 17, 18, 21, and 22 are rendered obvious.

Furthermore, Lee et al. does not disclose the amount of catalyst (Lipozyme TL IM) recited in instant claim 19 – Example 4 of Lee et al. speaks to the performing the method in a batch reactor. However, it would have been a matter of routine experimentation to have varied the amount of Lipozyme TL IM or substrate when performing the method of Example 4 of Lee et al., since the skilled artisan would have expected that the ratio of the Lipozyme TL IM to the substrate would have resulted in different yields of the resulting product obtained from the batch reactor. Further still, it would have been a matter of routine experimentation to have increased or lowered the amount of substrate depending on the amount of product desired. Therefore, in varying one of catalyst amount and substrate amount, instant claim 19 is rendered obvious.

A holding of obviousness is clearly required.

Claims 1-10 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., Sullivan et al., and Zhang et al. as applied to claims 1-4, 6-10, 17-19, 21, and 22 above, and further in view of Xu et al. (JAOCS. 2002. 79(6): 561-565. Listed on 9/17/07 IDS).

As discussed above, Lee et al., Sullivan et al., and Zhang et al. render claims 1-4, 6-10, 17-19, 21, and 22 obvious. However, they do not expressly disclose that when the Lee invention is performed in a packed bed reactor of the lipase with the soy oil mixture (e.g., Example 1), the

residence time of the oil in the catalyst bed of the packed bed reactor is less than 25 minutes, or less than 15 minutes, for the first hour of the process.

Xu et al. discloses obtaining various fat products by the lipase-catalyzed modification of oils and fats (page 561, first paragraph). In the study performed, oil was sent through a packed bed reactor of Lipozyme TL IM (page 561, second column, last two paragraphs). Various flow rates (residence times) were tested to determine their effect on the degree of reaction and the product (page 564, Figure 2). Residence times that were tested ranged from about 5 to about 150 minutes.

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have tested various residence times, including the residence times recited in instant claims 5 and 20, for performing the Lee invention in a packed bed reactor. One of ordinary skill in the art would have been motivated to do this since it would have yielded different fat/oil products, as demonstrated in Xu et al. Moreover, studying the effect of flow rate in a packed bed reactor is deemed suitable for demonstrating the promising aspects of the use of Lipozyme TL IM for interesterification (Xu et al., page 561, second columns, first full paragraph). Varying the residence times also would have been a matter of routine experimentation. Thus, instant claims 5 and 20 are rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed June 10, 2010, have been fully considered but they are not persuasive. The applicant asserts that Lee does not teach that enzymes which selectively

randomize sn-1 and sn-3 fatty acids can effect significant randomization at the sn-2 position at relatively low extents of conversion by selecting an enzyme activity that is above a threshold value because Lee is completely silent about the extent of sn-2 randomization. However, Examples 1 and 4 of Lee teach the use of Lipozyme TL IM, the preferred catalyst disclosed in the instant application comprising a Thermomyces lanuginosa lipase (page 10, lines 10-13). As the same catalyst disclosed in the instant application is used by Lee, the catalyst of Lee indeed is suitable for "An enzymatic rearrangement process for randomizing fatty acid residues on a triglyceride fat over the terminal and middle positions," the preamble recited in claim 1 under examination. Moreover, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., lipases which "selectively randomize sn-1 and sn-3 fatty acids" and can "effect significant randomization at the sn-3 positive at relatively low extents of conversion by selecting an enzyme activity that is above a threshold value") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Though Lee does not conduct measurement to differentiate between conversions of sn-2 fatty acids from conversions at the sn-1 or sn-3 fatty acids, this does not mean that conversion of sn-2 fatty acids (the middle positions of the fatty acid residues on a triglyceride fat) does not occur when treating triglycerides with Lipozyme TL IM in the method rendered obvious by Lee. First, though Lee et al. does not disclose that the lipase of the Lipozyme TL IM has an activity of at least 250 IUN at the onset of the process, the examiner has indicated that the creation of Lipozyme TL IM of different enzyme activities would have been a routine matter of

experimentation, as the skilled artisan would have recognized that the properties of the fats/oils produced would have varied according to enzymatic activity. Specifically, Lee indicates the enzymatic activity optimization is sought (page 6, paragraph [0062]) and that changes in lipase enzymatic activity can be followed by monitoring the transesterified fats and oils which have been treated by the lipase (page 6, paragraph [0064]). This demonstrates that the skilled artisan would have recognized that the lipase activity in general affects the properties of the fats/oils produced by the Lee method. Therefore, a result-effective variable is recognized as required by MPEP 2144.05. It is this line of reasoning discussed above that renders obvious the recited enzymatic activity of "at least 250 IUN at the onset of the process."

Furthermore, Lee teaches adjusting various parameters (flow rate, column residence time, temperature of the substrate mixture, etc.) after flowing the fat/oil through the lipase to optimize enzymatic activity (page 7, paragraph [0071]). Lee also teaches that temperature, light, and moisture content affect the lipase enzymatic activity (page 6, paragraph [0060]). Therefore, it would also have been obvious to have varied temperature, light, and moisture content to optimize the lipase enzymatic activity. It is the alteration of various parameters for the purpose of lipase activity optimization, and the use of Lipozyme TL IM of various initial enzymatic activities, including "at least 250 IUN at the onset of the process," that would have inherently resulted in the Re and Ra recited in the instant claims.

In response to applicant's argument that Lee nor any of the cited references recognizes that initial enzyme activity is a results-effective variable governing the extent of conversion of the sn-2 position (Ra), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability

when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Lee does not need to recognize producing appreciable rearrangement on the middle position of a triglyceride fat for the claimed invention to be rendered obvious.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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